OIPE JO180 SEP 30 2002 PATENT & TRADEMARK OFFICE

Patent
Attorney Dkt. No. 70482

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of Coppens et al.

Serial No.: 08/898,736

Filed: July 23, 1997

For: Process for the Preparation of Malted Cereal

Certificate of Mailing

I hereby certify that this paper is being deposited with the US Postal Service as first-class mail to: Commissioner of Patents & Trademarks, Washington, DC, 20231, on this date.

09/24/92 /Timothy E. Levstik/
Date Timothy E. Levstik
Reg. No. 30,192

Examiner C. Sherrer
Group Art Unit: 1761
Date: September 24, 2002

APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.F. § 1.192

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

This Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" mailed March 25, 2002.

I. REAL PARTY IN INTEREST

Cargill France N.V. is the assignee of the above-named patent application.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Appellants appeal the final rejection of claims 1, 3-9, 13-24, 27-31 and 43-83 which remain pending as of the filing date of this Brief. Appendix A presents the amended claims at issue. Independent claim 3 was amended in Amendment E, mailed October 3, 2001. Independent claims 1, 13, 18 and 27 were amended in Amendment F (Appellants' After Final Amendment), mailed May 16, 2002. The After Final Amendment corrected typographical errors to remove the first occurrence of "per gram" in the phrase "about 1 X 10^2 to about 1 X 10^7 per gram per gram of dry cereal."

IV. STATUS OF AMENDMENTS

In response to Appellants' Amendment E, mailed October 3, 2001, the Examiner issued a final rejection which was mailed December 26, 2001. In his final rejection, the Examiner rejected pending claims 1, 3-9, 13-24, 27-31, 33 and 43-83, (i) for failure to meet the requirements of 35 U.S.C. §112, (ii) for being unpatentable pursuant to 35 U.S.C. § 102, and (iii) for being unpatentable pursuant to 35 U.S.C. § 103. On May 16, 2002, Appellants filed an Amendment F after the final rejection for the purpose of correcting the typographical error described to put the claims into a better condition for appeal and allowance. The Examiner entered that amendment on May 23, 2002.

V. SUMMARY OF THE INVENTION

This invention is directed to a process for malting cereal grain having enhanced enzymatic activity over similarly prepared wetted cereal products with or without microorganisms. In certain applications, it is desirable to increase enzymatic activity in the malted product. This is desirable not only for certain beverage applications, but using the invention appears to permit a decreased level of toxins and an increased microbial safety by permitting desirable flora to out-compete undesirable flora such as Fussarium. (Spec. Pg. 13, middle to bottom.)

The process of the invention utilizes activated spores from microorganisms such as bacteria or molds. The inventors of the instant invention have discovered that the production of desirable enzymes is enhanced in malted cereal by mixing ***activated spores*** with the cereal and

water to provide the malted cereal with the enhanced enzymatic activity. The process generally comprises combining water, cereal and activated spores and then holding the combination until a malted cereal of enhanced enzymatic activity is formed. Generally the combination is made by inoculating the moistened cereal with the activated spores, but the activated spores and cereal may be combined before or after moistening of the cereal. The invention contemplates ***loading the malting environment with activated spores to create a new and unexpected enzymatic activity*** that does not exist without the use of activated spores or even with the use of dormant spores. (Spec. Pg. 5, top to Spec. Pg. 6, top.)

There is nothing new about activating spores. Activation is the start of spore germination. Medwid et al., *Germination of Rhyzopus Oligospores Sporangiospores*, Applied and Environmental Microbiology, Dec. 1984, at 1067 . **(Exhibit A.)** As part of germination (as would be the case for almost any seed), the spores swell and then develop germination tubes. The activated spores have one of the following properties: the treated spores are significantly more swollen than their dormant size, more particularly, the size of the spores is increased by a factor preferably between 1.2 and 10 over their dormant size and/or one or more germ tubes per spore are formed. The activated spores are prepared by subjecting them to environmental changes, preferably by one or a combination of the following treatments: cycles of wetting and/or drying; addition of appropriate nutritional supplies or spore elements; exposure to temperature changes; or exposure to changes in pH (Spec. Pg. 12, bottom to Pg. 13, top).

The activated spores may be introduced before or during the malting process. For example, the activates spores may be introduced during the various malting or steeping stages before or after immersion of the cereal. (Spec. Pg. 13, top.) It is these activated spores which are mixed with cereal and water to surprisingly provide enhanced enzymatic activity. (Coppens Decl., Sept. 16, 2001 ¶ .) **(Exhibit B.)**

The concentration of the spores may vary depending on the conditions of the malting process and the type of active spore being utilized. Generally the amount of activated spores has a range of about 1 x 10^2 to about 1 x 10^7 spores per gram of dry cereal being malted (Spec. Pg.13, top). **All of the claims describe mixing <u>at least</u> about 1 x 10^2 activated spores per gram of dry cereal** (Independent Claim 79). All of the remaining independent claims (1, 13, 18,

27, 48, 56, 64, 67 and 72) describe the amount of activated spores as a range of about 1 x 10^2 to about 1 x 10^7 spores per gram of dry cereal being malted. Not only do the claims describe using a specific amount of activated spores, ***the claims also require that the activated spores create an enzymatic activity which is comparatively greater than what would be created by the use of dormant spores***. More specifically, the claims require that the amount of activated spores be effective to increase the enzymatic activity of the malted cereal to a level greater than any increase resulting from the use of ***dormant*** spores in the malting process.

As will be seen, the prior art ***does not*** teach or suggest:

- mixing water, ***activated*** spores and cereal (Spec. Pg.5, top.);
- holding the water/activated spore/cereal combination to increase enzymatic activity (Spec. Pg.5, middle.);
- to use the activated spores to increase enzymatic activity over a blend of water and cereal without activated spores (Spec. Pg .6, top; Spec. Pg.30, top.); and
- a base level of 1 x 10^2 spores per gram of dry cereal of activated spores. (Spec. Pg. 13, top.)

IV. ISSUES

1. Does the Gyllang reference inherently disclose the claimed invention and anticipate it?

2. Does the Gyllang reference render the claimed invention obvious?

3. Is making activated spores enabled under 35 U.S.C.§112, first paragraph, to a person of ordinary skill in the art by the specification and available knowledge at the time the application was filed?

4. Does the term "activated spores" render the claims indefinite under 35 U.S.C.§112, second paragraph?

5. Does the phrase

> "the activated spores being present on the cereal in an amount which is effective for providing the malted cereal with an enzyme activity, the increased enzyme activity being greater than the enzyme activity which is obtained by the same malting process but with dormant spores"

render the claims indefinite under 35 U.S.C.§112, second paragraph?

6. Does the term "about" render the claims indefinite under 35 U.S.C.§112, second paragraph?

VII. GROUPING OF CLAIMS

For the Section 102(b) and 103 rejections:

Group I: Claims 1, 18, 48, 56 and 72, and their depending claims.

Group II: Claim 13, and its depending claims.

Group III: Claim 27, and its depending claims.

Group IV: Claim 64, and its depending claims.

Group V: Claim 67, and its depending claims.

Group VI: Claim 79, and its depending claims.

For ~~the~~ Section 112 rejections:

Class A: Claims 1, 13, 18, 27, 48, 56, 64, 67 and 72, and their depending claims.

Class B: Claim 79, and its depending claims.

Group I through V describes one group (which we call Class A) for the section 112 rejections.

Group VI forms the second group (which we call Class B) for the section 112 rejections.

The Claims have been placed in Groups I to VI for the art rejections and Classes A and B for the section 112 rejections. These Groups and Classes do not stand or fall together; each Group and Class is separately patentable.

VIII. ARGUMENT.

A. All Of The Claims Are Not Anticipated Or Rendered Obvious By Gyllang, The Sole Reference Applied By The Examiner In His 102(b) And 103 Rejections.

1. Gyllang, The Sole Reference

The sole reference applied by the Examiner is an article by Gyllang et al. **(Exhibit C.)** which describes adding certain ***metabolically inactive*** (or dormant) spores to barley during a malting process in the brewing of beer. Gyllang added three types of spores (A. fumigatus, A. amstelodami and Rhizopus oryzae) to malting barley to investigate whether these spores caused undesirable changes in the resulting beer. Gyllang stated:

> The object of the present investigation has been to clarify whether A. fumigatus and A. amstelodami – which have been found to cause gushing – give rise to changes in malt and wort which, in turn, lead to other qualitative changes in the beer. We also included studies of Rhizopus oryzae in this work because, although this fungus does not actually cause gushing, it has at times been rather prevalent in malt coming from the Swedish malting plant that has given gushing beer. Gyllang at page 247.

Gyllang expressly stated that the spores which they added were dormant:

> "On the other hand, the actual number of spores is probably of less importance than other factors since the spores themselves are metabolically inactive. It is instead the conditions prevailing during the germination period which are decisive-conditions which permit the spores to grow and develop mycelium with a high degree of activity which can affect the composition of the barley kernel."

As will be seen, the Examiner speculates that some of the spores in Gyllang's experiment might have grown during a germination period, but Gyllang never stated they did. Further, Gyllang is not a reference that would suggest to a worker to add activated spores to malt to achieve a desirable effect. The object of Gyllang was to confirm whether even the addition of dormant spores *had an adverse effect* on the resulting beer.

2. The Examiner's Art Rejection Based Upon Gyllang

The Examiner rejected the pending claims with an inherency type rejection. In the last final rejection the Examiner stated:

> Claims 1, 3-9, 13-24, 27-31, 33, 43-83 are rejection under 35 U.S.C. 102(b) as being anticipated by or in the alternative rejected under 35 U.S.C. 103 (a) as being unpatentable over Gyllang et al (European Brewing Convention (16th Congress)) for the reasons set forth in the last Office Action. Final Rejection SN 08/898,736 at page 7, mailed 12/26/01.

The "last office action" does not set forth the grounds of rejection. Several office actions ago, in an office action mailed about three years earlier on December 18, 1998, the Examiner did purportedly explain his art rejection at page 5 of that Office Action:

> Gyllang et al teach 'submitting [] barley grains to spore-infected steeping water (page 252). The organisms tested were Aspergillus fumigatus, A. amstelodami and Rhizopus oryzae. It stated that it 'is obvious, therefore, that the three fungi possess proteolytic, amylolytic and other carbohydrate-splitting enzymes which give noticeable effects under the conditions prevailing during the malting process.'(Page 248, bottom). It is considered that the added spores are activated spores because they have been grown on medium and then homogenized. This would produce spores that are no longer in the inactive state.
>
> The Office does not have the facilities for examining and comparing Applicant's (sic) product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant (sic) to prove that the claimed are functionally different than those taught by the prior art and to establish patentable differences. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 1977); Ex parte Gray, 10 U.S.P.Q. 2d 1922, 1923 (BPAI).
>
> Even if the prior art did not anticipate the claimed invention it is considered that it would have been obvious to those of ordinary skill in the art to use activated spores rather than inactive spores so that the benefits of Gyllang et al's disclosed increased enzymatic activity would be increased.
>
> While the cited article only states that the malting process involves steeping the barley as described on page 247, it is considered inherent that the broad moisture limitations recited in the claims are inherently met. See In re Best above. Even if the cited art does not anticipate the claimed moisture range, it would have been obvious to those of ordinary skill in the art to use standard and notoriously well known moisture contents for the malting process of Gyllang et al as those in the art can select and choose said limitations to optimize the malting process.

The December 1998 Office Action began Applicants' odyssey of amendments to more precisely define the claimed invention and declarations to show without contradiction that Gyllang et al. did not suggest or inherently practice the claimed invention. Now by repeating the art rejection of December 1998, Applicants respectfully submit that the Examiner without evidence, ***and indeed contrary to all of the evidence in the record,*** assumes that the process in Gyllang produces

activated spores in an amount which produces enhanced enzymatic activity as claimed. For the reasons set forth in detail below, Applicants respectfully submit that the Examiner has improperly rejected the claims in view of sections 102 and 103 of the Patent Code.

4. The Specification Has Defined Claim Terms

The specification defines "activated spore" as spores being swollen such that its size is increased by a factor of about 1.2 to about 10 over its dormant size and/or spores having one or more germ tubes per spore. See pages 10 to 11 of the specification. The specification also describes how to prepare activated spores:

> Activated spores are prepared by one or a combination of the following treatments.
> i) cycles of wetting and/or drying;
> ii) addition of appropriate nutritional supplies (such as a nitrogen source, preferably amino acids and/or a carbon source, preferably mono- or disaccharides) or spore elements;
> iii) exposure to temperature changes, preferably within a temperature range of about 0° to about 80°C;
> iv) exposure to changes in pH, preferably within a pH range of about 2.0 to about 8.0, more preferably about 3.0 to about 6.0. Specification at page 11.

Further the specification indicates the level of activated spores being mixed with the cereal and water:

> The concentration of the spores may vary depending on the conditions of the malting process and the type of active spore being utilized. Generally about 1×10^2 to about 1×10^7, preferably about 1×10^3 to about 1×10^5 activated spores per gram of air dry cereal is utilized. Specification page 13.

5. The Uncontradicted Proof Is That Gyllang's Spores Were Dormant And The Claimed Invention Provides Enzymatic Activity From A Malting Process That Is Greater Than A Malting Process Which Uses Dormant Spores.

(a) Gyllang's Spores Were Dormant

Gyllang grew his spores for three weeks at 20°C, homogenized the spores, *and then added* the homogenate to the malting cereal. As far as it its known, Gyllang immediately added the homogenate to the malting cereal, or left 0 hours for the homogenate to incubate and potentially activate. In the experiments conducted for the inventors of the instant application, the

homogenate was incubated not only for 0 hours (which was probably what Gyllang did if he immediately added the homogenate to the malting cereal), but also for 6 hours at 20°C and 42°C. Declaration of Coppens dated February 1, 2001, (Exhibit D.) Although Gyllang did not report an incubation of 20°C or 42°C for 6 hours, the inventors thought that the latter conditions would be more than enough to encourage spore activation if such activation was to occur by virtue of some unknown delay in Gyllang adding the spores to his malt. These experiments indicated that under any of the described conditions, *the spores did not activate, but rather remained dormant.* See Exhibit D, especially at paragraphs 15-18. In his February 1, 2001 declaration, after describing how the Gyllang work was repeated[1] and reporting the data collected, Theo Coppens, one of the named inventor's of the instant application swore:

> The data generated by the experiment described herein justifies my conclusion that the spore size distribution at incubation time - 6 hours, 20°C, and incubation time - 6 hours, 42°C for the three fungi tested is not statistically significantly different from the spore size distribution at incubation time - 0 hour and that the spores did not significantly increase in size upon incubation for 6 hours either at 20°C or 42°C. From this data, it should also be concluded that the spores prepared according to the Gyllang procedure, i..e., after 0 hours of incubation are not activated. Paragraph 18, Declaration of Coppens, dated February 1, 2001, Exhibit D.

(b) Mixing Activated Spores With Cereal Provides Greater Enzymatic Activity Compared To Mixing Dormant Spores In The Cereal.

The data in specification of this application proves a significant difference between the enzymatic activity of cereal malted with activated spores compared to dormant spores. See attached declaration of Coppens dated September 16, 2001, Exhibit B. The specification at page 20, Example I describes the activation of Rhizopus oryzae on TSB at pH 4 with an incubation for 5-6 hours at 42C°. The specification reports the following enhanced enzymatic activity using activated spores.

A_1 B_1 C_1 D_1

[1]Gyllang's work was repeated as best it could be due to the lack of detail reported in Gyllang's article. This lack of detail will be discussed infra.

	Traditional	Non Activated	Activated	Activated
β glucanase	214	371	683	3856
Xylanase	28	34	56	984

Example 3 at page 27 of specification further describes the activation of Rhizopus oryzae and the following enhanced enzyme activity.

	A_3	B_3	C_3
	Traditional	Non Activated	Activated
β glucanase	202	931	1322
Xylanase	43	65	71

This data confirms the viability of the invention which contemplates mixing activated spores with a cereal in sufficient quantity to improve enzymatic activity of the malt. (See page 13 of specification). The activated spores permit the production of enzymes which provide this improved activity. (See page 13 of specification).

(c) Close Analysis Of What Gyllang Did To His Spores Also Confirms That Gyllang's Spores Were Dormant (And Confirms Gyllang's Own Description Of His Spores As Metabolically Inactive).

Spores grow as if they were fruit on a small tree. During growth, the spores become remote from the nutrient and become dormant at the time of harvest. Gyllang put his spores into a peptone, yeast abstract and dextrose medium and grew them for three weeks. His spores grew as fruit on a tree and became remote from the nutrient medium and/or the medium may have become exhausted. Reference to the attached flow chart illustrates the cycle (Exhibit F). As a result, the spores became dormant. See attached declaration of Coppens dated September 16, 2001, at paragraphs 5-7, Exhibit B.[2] If the spores were activated at the time of Gyllang's

[2]The flow chart assumes Gyllang obtained his spores from the ATCC and grew them for about 7 days before he then grew them for three weeks. Also as will be discussed below, because the reference lacks detail, Gyllang can not be precisely duplicated, especially at the point where he added spores to his cereal. The

homogenization and then added to the cereal, they would have at least gown a germ tube after 6 hours at 20°C and 42°C. But as stated by Coppens in his February 1, 2001 declaration, no such germination tubes were observed after such time at such temperatures. Exhibit D at paragraph 17. Clearly, Gyllang did not add activated spores to his cereal.

6. Gyllang Does Not Anticipate Any Of The Claims.

(a) The Law Of Anticipation.

A prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently, to anticipate. Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitation, it anticipates. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, 49 U.S.P.Q.2d 1949, 1950-1951 (Fed. Cir. 1999); *Key Pharmaceuticals Inc. v Hercon Laboratories Corp,* 48 U.S.P.Q. 2d 1911 (Fed.Cir.1998); *Glaxo Inc. v. Novophaarm Ltd.*, 34 U.S.P.Q.2d 1565 (Fed.Cir.1995); *Continental Can Co. U.S.A. v. Monsanto Co.*, 20 U.S.P.Q.2d 1746 at 1749 (Fed. Cir. 1991). In his Office Action the Examiner cited of *In re Best*, 195 U.S.P.Q. 430 (C.C.P.A. 1977). *Best* does not advance the Examiner's position. In *Best* the applicant claimed a process where a cool down rate was important. The Examiner cited a reference that apparently described applicant's claimed process, but did not describe a cool down rate. The C.C.P.A. held that applicant had not shown the reference did not inherently describe the claimed process because the applicant never comparatively tested the cool down rates to show that his product was not formed by the process of the reference where a typical cool down rate was used. See *Best* at 195 U.S.P.Q. at 433. That is not the case in the instant application. The process of the claimed invention is certainly not identical to Gyllang. Gyllang said that he used metabolically *inactive or dormant spores.* The data in the specification shows that the enzymatic activity resulting from the claimed process is different using dormant versus activated spores. Duplication of Gyllang's spore cultivation confirms that Gyllang did indeed add dormant spores to his process. Declaration of Coppens,

---

Coppens February 1, 2001 declaration (Exhibit D) describes only the growing and harvesting spores which is Coppens' best estimate of what Gyllang actually did to prepare his spores.

February 1, 2001, Exhibit D.[3]

(b) The Group I Claims - 1, 18, 48, 56 and 72 Are Not Anticipated.

Gyllang could only anticipate the claims 1, 18, 48, 56 and 72 if Gyllang mixed *activated* spores with his barley. Gyllang does not describe mixing activated spores into the malting barley, it describes mixing ***metabolically inactive*** (or dormant) spores into the malt.

Second, Gyllang does not describe mixing *any level* of activated spores into a malting barley. Hence, because all of the Group I claims require activated spores being mixed with water and barley at al level of about 1×10^2 to about 1×10^7 activated spores per gram of dry cereal, Gyllang cannot anticipate these claims.[4] The past declarations, the scientific literature and the specification's description of an enzymatic activity which is comparatively greater than what would be created by the use of dormant spores of Gyllang, conclusively prove that Gyllang did not mix activated spores into his cereal to malt it.

Third, all of the Group I claims also require that the activated spores create an enzymatic activity which is comparatively greater than what would be created by the use of dormant spores.[5] Even if Gyllang described activated spores or if activated spores were inherent in Gyllang's malting process (which they are not as will be seen infra), the concepts of the claimed invention (i) having a base level of activated spores of about 1×10^2 to about 1×10^7 activated spores per gram of dry cereal to provide (ii) an enzymatic activity which is comparatively greater than what would be created by the use of dormant spores, is not remotely described or suggested by Gyllang.

(c) The Group II Claim 13 Is Not Anticipated

---

[3]The Coppens Declaration of February 1, 2001 repeated work described in an earlier Coppens declaration dated March 3, 2000 (Exhibit E). The Examiner demanded statistical analysis of data which required the repeat of experiments and then the statistical analysis memorialized in the Coppens Declaration which is Exhibit D.

[4]As can be seen, the Examiner's anticipation rejection ignores all the data in the specification and declaration evidence in the record that the spores which Gyllang added to the barley were dormant.

[5]In addition to the specification describing the increased enzymatic activity created by activated spores over that which is created by dormant spores, Applicants also submitted a declaration confirming their data and findings. Coppens Declaration dated September 16, 2001, Exhibit B.

Claim 13 is not anticipated for the same reasons as the Group I claims are not anticipated. Claim 13 further provides, however, that the cereal in a moistened/activated spore combination be germinated and later dried. Gyllang does not describe or even suggest this combination with the increased activity activated spores provide over the addition of dormant spores.

(d) The Group III Claim 27 Is Not Anticipated

Claim 27 is not anticipated for the same reasons as the Group I claims are not anticipated. Claim 27 further provides, however, that the cereal be steeped to a moisture content of 20% to 60% by weight, the cereal be germinated for 2 to 7 days in the presence of activated spores, and then the steeped, germinated cereal is dried. Gyllang does not describe when the dormant spores were added, how long they were in the malt, the amount of spores or the concentration of the spores added or even how many spores were grown before the spores were added to the malt. Gyllang does not describe or even suggest the combination of Claim 27, or the increased in activity activated spores provide over the addition of dormant spores.

(e) The Group IV Claim 64 Is Not Anticipated

Claim 64 is not anticipated for the same reasons as the Group I claims are not anticipated. Claim 64 specifies barley and further provides, however, that a) the increased in enzyme activity be β- glucanase, xylanase, amylase, Protease, naturally occurring enzymes in the barley, b) the activated spore, water, barley mixture be held at 5° to 30° C to provide a wetted barley having a moisture content of at least 20%, and c) activating the spores by cycles of wetting and drying, addition of nutritional supplies, exposure to temperature changes within a range of about 0° to about 80°C, exposure to changes in pH within a pH range of about 2.0 to about 8.0 to obtain spores where the size of the spores is increased by a factor between about 1.2 and about 10 over their dormant size and/or the spores have one or more germ tubes per spore. Not only does Gyllang not describe the latter combination, Gyllang does not describe the activation of any spores or the increased activity activated spores provide over the addition of dormant spores.

(f) The Group V Claim 67 Is Not Anticipated

Claim 67 is not anticipated for the same reasons as the Group I claims are not anticipated. Claim 67 specifies barley and further provides that a) the increased in enzyme activity be β-glucanase, xylanase, amylase, Protease, naturally occurring enzymes in the barley, b) the activated

spore, water, barley mixture be held at 5° to 30° C to provide a wetted barley having a moisture content of at least 20%, and (c) the wetted barley be germinated for about 2 to about 7 days at 10° to 30° C to increase enzyme activity. Gyllang does not describe mixing activated spores with barley as claimed, Gyllang does not describe the level of spores added or how long the spores are in the malting mixture, nor does Gyllang describe the increased activity provided by activated spores over the addition of dormant spores in the same type of process.

(g) The Group VI Claim 79 Is Not Anticipated

Claim 79 is not anticipated for the same reasons as the Group I claims are not anticipated. Claim 79 specifies barley and further provides, however, that a) the increase in enzyme activity be β- glucanase, xylanase, amylase, Protease, naturally occurring enzymes in the barley, b) the activated spore, water, barley mixture be held at 5° to 30° C to provide a wetted barley having a moisture content of at least 20%, and (c) the wetted barley be germinated for about 2 to about 7 days at 10° to 30° C to increase enzyme activity. As noted with the other claim groups, Gyllang does not describe mixing activated spores with barley as claimed, Gyllang does not describe the level of spores added or how long the spores are in the malting mixture, nor does Gyllang describe the increased activity provided by activated spores over the addition of dormant spores in the same type of process.

6. Gyllang Does Not Render Any Of The Claims Obvious.

(a) The Law Of Obviousness

Obviousness is a legal conclusion based upon factual evidence. To reach a proper conclusion of obviousness, the decision maker must step backward in time and into the shoes of a person of ordinary skill in the art when the invention was unknown and just before it was made. In the light of all the evidence, the decision maker must then determine whether the claimed invention as a whole would have been obvious at that time to that person. The Patent and Trademark Office has the burden to establish a *prima facie* case of obviousness. It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to come the relevant teaching of the references. *In re Dembeczak*, 50 U.S.P.Q. 2d 1614 at 1618 (Fed. Cir. 1999); *In*

re Fine, 5 U.S.P.Q. 2d 1596 at 1598 (Fed. Cir. 1988). There also must be some suggestion or incentive established in the prior art for making the claimed invention. *In re Fine*, 5 U.S.P.Q. 2d at 1599. The Examiner points to nothing substantive in the cited Gyllang reference which suggests or teaches the claimed invention which uses activated spores. Instead, the Examiner speculates against the evidence that Gyllang activated spores and then added those activated spores to his malting process. Then using hindsight in combination with Applicants' specification, the Examiner concludes that the pending claims are obvious based upon the incorrect premise that activated spores must have been made and added to the malting process described by the reference.

(b) The Examiner Did Not Establish Prima Facie Obviousness

The invention contemplates loading malting environment with activated spores to create a new and unexpected enzymatic activity that does not exist without the use of activated spores or even with the use of dormant spores. The claims distinguish Gyllang because the increased enzyme activity is defined as being greater than the enzyme activity which is obtained by a malting process with spores which are not activated.

Nothing in Gyllang points to adding activated spores to a malting process. Gyllang conducted his study to determine if certain spores in a malting process were undesirable. His study never concluded they were desirable.

Gyllang added dormant spores ***and said so.*** The February 1, 2001, Coppens declaration (Exhibit D) also proves Gyllang added dormant spores. Under the circumstances of Gyllang's experiment, Gyllang does not even impliedly suggest adding activated spores.

Further, Gyllang stated:

> "On the other hand, the actual number of spores is probably of less importance than other factors since the spores themselves are metabolically inactive. It is instead the conditions prevailing during the germination period which are decisive-conditions which permit the spores to grow and develop mycelium with a high degree of activity which can affect the composition of the barley kernel." (Gyllang page 252)

In contrast to the present invention, Gyllang did not consider the number of spores he added as important. Increasing the number of spores might be considered as analogous to activation of spores. If the number of spores was not important as taught by Gyllang, one would

not be taught by Gyllang to add activated spores. See paragraph 7, Coppens Declaration dated February 1, 2001, Exhibit D). Rather, Gyllang focused on germination conditions with dormant spores which the data in the applicants' specification show are clearly not as important as the addition of activated spores. Further, one of ordinary skill would not expect his malting process to have a substantially enhanced activity if one were to add not only dormant spores, but also mycelium as a part of the addition of dormant spores to the malting cereal.

It is true that Gyllang stated:

> "It is obvious, therefore, that the three fungi possess proteolytic, amylolytic and other carbohydrate-splitting enzymes which give noticeable effects under the conditions prevailing during the malting process." Gyllang, page 248.

That phenomenon is not new. The specification at page 3 cites WO 94/29430, The European Brewery Convention, volume 16, 1977. Also see WO 94/16053. A key to the instant invention is the addition of activated spores to get more enzymatic activity faster than any addition of dormant spores.

Against all the objective data, the Examiner quotes a snipet from page 252 of Gyllang,

> "a high degree of activity that can affect the composition of the barley kernel."
> See page 7 of Office Action of December 26, 2001.

The Examiner then concludes without any evidence whatsoever that one of ordinary skill would be motivated to use activated spores and Gyllang desired use of germinated growing fungi and to activate fungi. Pages 7-8 of the Office action of December 26, 2001. Those conclusions are simply not true, are contrary to what Gyllang did and what Gyllang stated, and also are contrary to the evidence of the declarations and specification.

By focusing on an increased activity of enzymatic activity, the amended claims clearly distinguish the phenomenon described by Gyllang of possibly developing an activity during malting with inactivated spores. At minimum, the invention "gets more enzymatic activity faster" because it uses activated spores, see examples 1 and 3 in the specification. This proves patentability not a prima facie case of obviousness.

Because of the lack of detail in Gyllang's description of his malting process, that process could not be duplicated to prove a lack of enzymatic activity. See paragraph 8 of the Declaration

of Coppens dated September 16, 2001, Exhibit B. Gyllang does not report the amount of spores and the concentration of spores which he added to his barley. We do not know how many spores he grew after three weeks in the Peptone. We do not know the volume of steep water in the second steep when Gyllang added the dormant spores. The data showing dormant spores in the Coppens declaration[6] and the data shown in the specification (and confirmed by separate declaration of Coppens dated September 16, 2001, at paragraphs 3-4, Exhibit B), showing the enhanced enzymatic activity created by activated spores over dormant spores, is the best experimental data available which shows that Gyllang added dormant spores to his malting process. The same data also shows the significant and unexpected results of the invention over the use of dormant spores. The data proves the non-obviousness of the applicants' invention.

Finally, the Examiner's conclusions as to obviousness in view of Gyllang assume that a worker of ordinary skill would know how to activate spores and spore activation inherently taking place under Gyllang's malting conditions. The latter premise and conclusion is fundamentally inconsistent with the Examiner's section 112 rejection to the effect that Applicants' specification is not enabling. See paragraphs 5, 6, and 9-13 of the December 26, 2002, Office Action.[7] The Examiner in concluding obviousness (i) presumed Gyllang added activated spores and (ii) presumed Gyllang suggested that the activated spores be added to a malt when Gyllang did not say a word about spore activation. Hence in his art rejection, the Examiner concludes that Gyllang enabled and taught a worker with ordinary skill to activate spores and then added activated spores to a malt. That is not consistent with the Examiner's section 112 rejections where the Examiner concludes Applicants' invention is not enabled because a worker of ordinary

---

[6]As previously noted, the Examiner at first requested that Applicants conduct an experiment showing the dormancy of Gyllang's spores. Interview Summary, February 18, 2000, Exhibit G. When Applicants conducted such an experiment (See Coppens Declaration dated March 3, 2000, Exhibit E), he chose not to believe the results and demanded statistical verification. Applicants then redid their experiments and provided statistical verification for their conclusions. February 1, 2001, Coppens Declaration, Exhibit D. To no avail, the Examiner continued not to accept the results of Applicants' experiments and chose to continue his rejection. See the Office Action dated March 15, 2000.

[7]The Examiner's sweeping conclusions as to what Gyllang teaches as to spore activation and the addition of activated spores to a malt are even more surprising in view of the Examiner's admission, "he is not an expert in the field of spore technology." See pages 3-4 of the Office Action dated December 26, 2001.

skill would not have known how to activate spores.[8]

A. The Examiner's Newly Asserted Rejections Under Section 112 Are Not Well Taken.

1. The Section 112 Rejections

The Examiner has asserted rejections under the first and second paragraphs of section 112. These rejections are new or at least had not been asserted until an April 10, 2001, Office Action (in an application which Applicants filed July 23, 1997). The Examiner repeated the April 2001, Section 112 rejections in his last Office Action dated December 26, 2001 which Applicants now appeal.

Prior to the April 10, 2001 Office Action, the Examiner had Applicants busily doing work and filing declarations which not only show that Gyllang mixed dormant spores in his malting process, but also provide data which proves that adding dormant spores to a malting process did not provide the enzymatic activity compared to adding activated spores.

Starting with the April 2001 Office Action, the Examiner now has rejected all of the claims (1) for not being enabled (35 USC §112, first paragraph) principally because the specification purports not to enable a person of ordinary skill to activate spores; and (2) for being indefinite under 35 USC §112, second paragraph. The claims purportedly are indefinite under 35 USC §112, second paragraph because the scope of the term "activated spores" is indefinite and/or it is unclear as to what point the malting process of the invention provides an increased activity over a process using dormant spores. The Examiner did not assert these rejections until his April 2001 Office Action although he asserted his Gyllang art rejection in five Office Actions prior to his April 2001 Office Action. In short the Examiner ***has not*** avoided piecemeal examination as he should have MPEP §707.07(g).

Finally, the Examiner rejected the claims for the use of the term "about" (35 USC §112, second paragraph) and that the declaration as to the ATCC deposit did not specify when certain microorganisms were deposited and available to the public.

---

[8]The baselessness of the Examiner's enablement rejection will be discussed infra.

(a). The Law Of Enablement.

The test for enablement is whether one skilled in the art could make and use the claimed invention from the disclosure coupled with information known in the art without undue experimentation. *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), cert. denied, 109 S.Ct. 1954 (1989); *In re Stephens*, 529 F.2d 1343, 1345, 188 USPQ 659, 661 (CCPA 1976).

In order to make such a rejection, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). The Examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure. A disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to terms used in the claims must be taken as being in compliance with the enablement requirement of 35 USC §112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Unless there is sufficient reason for such doubt, a rejection for failure to teach how to make and/or use is improper. *In re Bowen*, 181 USPQ 48 at 51 (CCPA 1974); *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). As stated by the *Marzocchi* court,

> it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure. *In re Marzocchi*, 439 F.2d at 224, 169 USPQ at 370.

If the Examiner establishes a reasonable basis to question the enablement provided for the claimed invention, the burden falls on the applicant to present persuasive arguments, supported by suitable proofs where necessary, that one skilled in the art would be able to make and use the claimed invention using the disclosure as a guide. *In re Brandstadter*, 484 F.2d 1395, 1406, 179 USPQ 286, 294 (CCPA 1973). In making the determination of enablement, the Examiner must consider the original disclosure and all evidence in the record, weighing evidence that supports

enablement against evidence that the specification is not enabled. MPEP §2164.05.

(b). The Specification, The Art And Articles As Of The Time Of The Filing Of This Application Teach How To Activate Spores.

The specification of the instant applications of the instant application describes how to activate spores:

"Activated spores are prepared by one or a combination of the following treatments.

i) Cycles of wetting and/or drying;

ii) addition of appropriate nutritional supplies (such as a nitrogen source, preferably amino acids and/or a carbon source, preferably mono- or disaccharides) or spore elements;

iii) exposure to temperature changes, preferably within a temperature range of about 0° to about 80°C;

iv) exposure to changes in pH, preferably within a pH range of about 2.0 to about 8.0, more preferably about 3, to about 6.0." Specification, page 11.

Art cited by the Examiner describes activation as the start of germination. See Medwid et al. "Germination Of Rhyzopus oligospores etc.", Applied and Environmental Microbiology 1984 p. 1067-1071, at the Abstract, Exhibit A. Applicants submit that in view of their specification and art cited by the Examiner, the invention has been enabled: a person of ordinary skill would know how to start the germination of a spore or how to activate it.

Even assuming arguendo that the Examiner did establish some doubt about how the specification describes how to activate a spore, Applicants submit that they have supplied more than enough evidence which proves that a person of ordinary skill could activate a spore and practice the claimed invention.

The Examiner does not deny that he admitted that if a spore forming organism is on deposit, the spore can be germinated and is enabled (The Examiner made his admission during an interview on August 14, 2001 and memorialized it in an Interview Summary, Exhibit H). The premise is simply that if a spore forming organism is on deposit, that deposit is often dormant or in a freeze dried state of dormancy. After the deposited organism is ordered by a user, it is sent to the user to make spores and germinate them. If it were otherwise, the deposit system would not work. In his last Office Action the Examiner attempts to disingenuously elude his agreement on the point by saying:

> The examiner, in his quest to educate himself on the technology of germinating spore, relied on the representations from applications, in the last interview, to come to this

conclusion. The examiner admits that he is not an expert in the field of spore technology. Therefore, any admission by the examiner is based on information provided by applicants or discovered by the examiner in his search. The examiner notes that knowing that one 'can' activate a spore does not equated to 'knowing how to' activate a spore. Office Action, December 26, 2001 at pages 3-4.

The Examiner provides no additional information that if a spore forming microorganism is on deposit, a person of ordinary skill would not know how to activate and then completely germinate the spore. Indeed, at paragraph 10 of his last Office Action of December 2001 he described literature provided by the Applicants which as of the date of the application would have described to a worker additional conditions to consider in activating spores.

In any event, acting on the Examiner's agreement that if a spore forming microorganism is on deposit, Applicants filed the October 3, 2001 declaration of James P. Krueger (Exhibit I) that the organisms described in the claims are on deposit. That list of microorganisms is set forth in Exhibit J (That list was filed with the Krueger declaration, Exhibit I).

Further to confirm that a person of ordinary skill would know how to germinate and/or activate spores, Applicants supplied the Examiner with articles located in a review of the literature showing just how to carry out such activation. These articles were listed as set forth below and are identified by tab number in a second October 3, 2001 Krueger declaration (Exhibit L) :

Bacillus spp. Turian Table 2 (no page #) #8
General Microbiology pg. 75 #10

Venturia spp. Fungal Physiology, Griffin Table 1, pg 262, #9 describes water content, and how to germinate.

Saccharomyces spp. Fungal Physiology, Griffin Table 1, pg 262, #9 describes water content, and how to germinate.

Neurospora spp. The Fungal Spore, Weber, pg. 124 # 6
The Fungi Ainsworth pg 754 #4
Smith et al. Filamentous Fungi Table 18.1 pg 359 #7.

Mucor miehel Smith et al. Filamentous Fungi Table 18.1 pg 359 #7.
The Fungal Spore, Weber, pg. 111 # 6

Rhizopus spp. The Fungi Ainsworth pg 746 #4

Rhizopus arrhizus Ekundayo, the Examiner already has article.

Rhizopus oligosporus, Medwid, the Examiner already has article.

Rhizopus oryzae, specification page 15.

Rhizopus chinensis, Physiology of Fungi, Cochrane, pg 406, Table 3, # 2.

Rhizopus delemar Fungal Physiology, Griffin Table 4, pg 275, #9

Aspergillus spp., Physiology of Fungi, Cochrane, pg 404-405, humidity specified, # 2.
Tsay et al Transient Effect of Exogenous etc., article describes germination conditions, #12.

Aspergillus nidulans, Osherov et al., (2001 article), see pages 154, 156 and 157, #11.

Aspergillus niger, The Fungus Spore, Madelin pg. 159 # 5
Smith et al. Filamentous Fungi Fig. 18.2 pg 365 #7.

Aspergillus oryaze, Specification
The Fungi Ainsworth pg 746 #4

Penicillum spp., Physiology of Fungi, Cochrane, pg 404-405, # 2. (All of the tabbed articles are part of the record and for the sake of brevity have not been attached as Exhibits.)

In view of the specification, the Medwid reference cited by the Examiner, the large number microorganisms of the claims which are deposited, and the numerous articles which describe how to activate and germinate spores, Applicants respectfully submit that there is no doubt that activation as described in the claims and the specification of the instant application is enabled. Applicants respectfully request that the Examiner's "enablement" rejection under section 112 of the Patent Code be reversed.

(c) The Deposit Requirements Have Been Met And The Declarations Of James P. Krueger Obviate The Rejection Based Upon Lack Of Deposit.

The October 3, 2001 declaration of James P. Krueger (Exhibit K) proves that the following microorganisms are on deposit with the American Type Culture Collection:

a) Rhizopus Oryzae NRRL 1427, now assigned PTA-3670;

b) Rhizopus Oryzae NRRL 1891, now assigned PTA-3671;

c) Rhizopus Oryzae ATCC 4858, now assigned PTA-3627;

d) Aspergillus Oryzae ATCC 14156, now assigned PTA-3628; and

e) Rhizopus Oryzae ATCC 9363, now assigned PTA-3629.[9]

After the October 3 Krueger Declaration, the Examiner then asserted a new objection to the second October 3, 2001 Krueger Declaration which lists the microoganisms set forth in Exhibit J and their availability in the ATCC. Exhibit I. The Examiner questioned the dates of availability of the microoganisms. See paragraph 6 of the December 26, 2001 Office Action. Responsive to the December 2001 objection, James P. Krueger filed yet a fourth declaration confirming the dates of deposit of specific microorganisms prior to the filing of the instant application (Exhibit M). Applicants respectfully assert that the four Krueger declarations obviate the Examiner's "deposit" objections.

(d) The Law Of Claim Definiteness

The second paragraph of 35 U.S.C. §112 states:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The claims are not read in a vacuum and are to be interpreted in light of the specification giving them their broadest reasonable interpretation. *In re Maarosi,* 218 U.S.P.Q. 289, 292 (Fed.Cir.1983). The scope of the claims should be reasonably ascertainable by those skilled in the art. *Ex parte Porter*, 25 U.S.P.Q. 2d 1144, 1146 (Bd.Pat.App.Int'f. 1992). Against this background, the phrase "an effective amount of a germicide suitable for use in oral hygiene" was held not to be indefinite. *In re Watson*, 186 U.S.P.Q. 11, 20 (C.C.P.A. 1975). The phrase "to substantially increase the efficiency of the compound as a copper extractant from aqueous solutions having a pH of less than about 1" also was held not to be indefinite. *In re Mattison,* 184 U.S.P.Q.484, 486 (C.C.P.A. 1975).

Further, the term "about" does not render a claim indefinite, especially where the specification provides an indication as to what range of activity is covered by the term. *Eiselstein*

---

[9]This October 3, 2001 declaration (Exhibit K) was responsive to an objection asserted by the Examiner in his April 10, 2001 Office Action stating specific strains of microorganisms needed to be deposited and releaseable to the public once the patent issues.

v. Frank, 34 U.S.P.Q. 2d 1467, 1471 (Fed. Cir. 1995); *Gore & Assoc. Inc. v. Garlock*, 220 U.S.P.Q. 303, 316 (Fed. Cir. 1983); *Syntex, Inc. v. Paragon Optical Inc.*, 7 U.S..P.Q. 2d 1001, 1038 (D. Arizona 1987); MPEP §2173.05(b)(A).

(e) The Claims Are Not Indefinite

The specification not only tells how to activate spores, it defines the terms "germination" and "activated spores". The specification states in pertinent part:

> The process of the invention utilizes activated spores from microorganisms such as bacteria or moulds. The process generally comprises combining water, the cereal and activated spores and holding the combination until a malted cereal of enhanced enzymatic activity is formed. Specification, page 5.
>
> * * *
>
> In the process of the invention, the combination of wetted cereal and activated spores has a concentration of activated spores, holding time and holding temperature which are effective for providing the malted cereal with an increase in enzymatic activity of at least one enzyme...." Specification page 5.
>
> * * *
>
> [T]he cereal, activated spores are combined before or after the time of wetting the cereal and the combination is held at a temperature of at least about 5°C and not more than about 30°C, preferably between about 10°C to about 20°C. Specification page 5.
>
> * * *
>
> In still another important aspect, the moistened cereal and activated spores are held together until the cereal has a moisture content of between about 20 to about 60 weight percent, preferably form about 38 to about 47 weight percent and has germinated for about 2 to about 7 days, preferably about 3 to about 6 days, at a temperature of from about 10° to about 30°C, preferably from about 14° to about 18°C. Specification pages 5-6.
>
> * * *
>
> As used herein the term 'activated spore' means a spore having one of the following properties:
> i) The spore is swollen such that its size is increase (sic) by a factor of between about 1.2 and about 10 over its dormant size; and/or
> ii) one or more germ tubes per spore is formed. Specification pages 10-11.

Against this background, the Examiner asserts that the term "activated spores" is indefinite. In view of the fact that (i) the specification teaches how to activate spores, (ii) the art at the time the instant application was filed recognized how to activate spores, and (iii) in view of the definition "activated spores" in the specification, Applicants respectfully assert that the scope

of the term "activated spores" in the claims should be reasonably ascertainable by those skilled in the art.

The Examiner also has asserted that the phrase "an increased activity of an enzyme compared to the activity of an enzyme obtained by moistening and mixing the cereal with dormant spores" is indefinite purportedly because it is not clear at what point the increased enzyme activity is measured. See page 6-7 of the December 26, 2001 Office Action. Applicants assert that the Examiner has ignored the specification. The specification generally states that the combination of wetted cereal and activated spores has a concentration of activated spores, holding time and holding temperature which are effective for providing the malted cereal with an increase in enzymatic activity of at least one enzyme. Then the specification more specifically states that the moistened cereal and activated spores are held together until the cereal has a moisture content of between about 20 to about 60 weight percent, preferably form about 38 to about 47 weight percent and has germinated for about 2 to about 7 days, preferably about 3 to about 6 days, at a temperature of from about 10° to about 30°C, preferably from about 14° to about 18°C. Applicants assert that the time at which enhanced activity is to be expected and measured would be reasonably ascertainable by those skilled in the art.

Finally the Examiner objects to the use of the term "about" in the range of spores being mixed with the cereal. Applicants assert that the rejection is not well taken in view of the general description of the specification saying the combination of wetted cereal and activated spores has a concentration of activated spores, holding time and holding temperature should be effective for providing the malted cereal with an increase in enzymatic activity of at least one enzyme. That general statement together with the range of 1 x 10^2 to about 1 x 10^7, preferably about 1 x 10^3 to about 1 x 10^5 activated spores per gram of air dry cereal as suggested ranges, make the meaning of term "about" reasonably ascertainable by those skilled in the art.

(f) The Group VI Claims Are Not Indefinite Because They Do Not Have An Upper Limit On The Activated Spore Range

Claim 79 provides a pertinent part:

> 79. A method for the preparation of a malted barley, the method comprising: mixing activated spores, a barley and water to provide a malting barley composition, the activated spores being present in an amount of at least about 1 x 10^2 per

gram of air dry barley to provide a malting barley composition, the amount of activated spores being effective for providing an increased enzyme activity greater than the enzyme activity which is obtained by the same malting process which includes dormant spores an wherein the increased enzyme activity is selected from the group of β-glucanase, xylanase, amylase, Protease, naturally occurring enzymes in the barley and combinations thereof....

The specification states at page 13:

> The concentration of the spores may vary depending on the conditions of the malting process and the type of active spore being utilized. Generally about 1×10^2 to about 1×10^7, preferably about 1×10^3 to about 1×10^6 activated spores per gram air dry cereal is utilized.

Even though there is no upper limit for the range of the amount of activated spores being mixed with the barley,[10] Applicants respectfully assert that in view of (i) the general description of adding activated spores to cereal to achieve an enhanced enzymatic activity, (ii) the description of the type of enzymes, as well as (iii) a suggested upper limit to the range in the specification, the scope of claim 79 et seq. is reasonably ascertainable by those skilled in the art.

CONCLUSION.

In view of the foregoing materials, declarations and amended claims, applicants respectfully request reconsideration and allowance of the pending claims.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

By: 

Timothy E. Levstik
Registration No. 30,192

Date: September 24, 2002
Fitch, Even, Tabin & Flannery
120 So. LaSalle St., S/1600
Chicago, IL 60603-3406
Telephone: 312/577-7000
Facsimile: 312/577-7007

[10] All of the other independent claims have a 1×10^2 to 1×10^7 per gram of cereal range.